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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/783,967	02/16/2001	Daniel E. Alesi	0100/0118	2936

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SERKE, CATHERINE

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

3763

DATE MAILED: 07/01/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/783,967	ALESI, DANIEL E.
	Examiner	Art Unit
	Catherine Serke	3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 20 June 2003.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 24-52 is/are pending in the application.
- 4a) Of the above claim(s) 24-38 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 39-52 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)      4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) Notice of Informal Patent Application (PTO-152)  
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.      6) Other:

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 44 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new claim language of "one piece" is not adequately disclosed in the specification to convey to one skilled in the art the meets and bounds of this limitation. The drawings show a device for shielding a needle that has many parts or components and therefore this recitation appears contrary to the invention shown.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 45-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 45-47 recite the limitation "Safety" in the preamble. There is insufficient antecedent basis for this limitation in the claim now that "safety" has been deleted from claim 44.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 39-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sweeney et al (US Pat# 5,746,726) in view of Newby et al (US Pat# 6,436,086).

Sweeney discloses a device that includes a body (52) with a needle (14) extending from one end and another end that is attached to a syringe (fig 3). A housing (36) is hingedly (50) attached to the end of the body having the needle and is pivotable to a position in substantial alignment along the longitudinal axis of the body so as to envelop the needle (fig 2). Locking means (56) are integrated to the housing for fixedly retaining the needle within the housing once the needle is enveloped by the housing (fig 5). The locking means comprises at least one pair of fingers or hooks (56) that prevent the needle from being removed from the housing once the housing is pivoted to envelope the needle (fig 5). Another locking means (58) is on the body that coacts with the locking means on the housing.

Sweeney meets the claim limitations as described above but fails to include the body being connected to tubing instead of a syringe at the other end from the needle. However, Newby discloses a safety shield for a medical needle (fig 17) that has a housing (140a) hingedly connected to a body (90a) having a needle (206). Additionally, on the opposite side of the body from the needle is connected flexible tubing (208). The other embodiments show the pivotable housing attached to a syringe and a vacutainer port.

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At the time of the invention, it would have been obvious to substitute the syringe of Sweeney for flexible tubing as taught by Newby. The devices are analogous in the art and therefore a combination is proper. Additionally, both devices are functional equivalents and utilize a pivotably hinged housing in order to protect a medical technician from being exposed from a needle stick. The motivation for the incorporation would have been in order to provide the device of Sweeney with an alternate means of blood collection thereby enabling more blood to be collected in a container (i.e. a blood bag) at the end of the flexible tubing.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

- (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
- (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 39-41, 44-46 and 48-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Newby et al.

Newby discloses a safety shield for a medical needle (fig 17) that has a housing (140a) hingedly connected to a body (90a-204) having a needle (206). It is considered inherent that the body includes a through passage connecting its one end to its other end in light of the fluid delivery function of the device. The proximal portion of the body (204) has wings (see figure 17). Additionally, on the opposite side of the body from the needle is connected flexible tubing

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(208). A locking mechanism, analogous to applicant's locking means, is best seen in figure 16. Hooks or fingers (194) hold the housing in the retaining needle position by their connection with element 118. Furthermore, figure 17 best shows the intravenous device body construction where the body is integrally (meaning used: "formed as a unit with another part") attached to the tubing, needle and housing. The definition of the term integral appears below in the Response to Arguments. Finally, the device is considered one-piece once assembled and during use.

#### *Response to Arguments*

Applicant's arguments filed 5/27/03 have been fully considered but they are not persuasive. The term integral as defined in Merriam Webster's Collegiate On-Line Dictionary is "**1 a** : essential to completeness : CONSTITUENT <an *integral* part of the curriculum> **b** (1) : being, containing, or relating to one or more mathematical integers (2) : relating to or concerned with mathematical integrals or integration **c** : formed as a unit with another part <a seat with *integral* headrest>; **2** : composed of integral parts; **3** : lacking nothing essential : ENTIRE

- **in·te·gral·i·ty** /"in-t&-'gra-l&-tE/ *noun*

- **in·te·gral·ly** /"in-ti-gr&-lE; in-'te-gr&- also -tE-/ *adverb*" (<http://www.merriam-webster.com/cgi-bin/dictionary>). Definitions 1a, 2 and 3 only are pertinent to the use in the instant claims.

This term is broad. The crux of applicant's argument is that since the prior art teaches devices manufactured from separate pieces the prior art fails to read on the recitation of an integral device. The term integral as defined above and as generally used in the art does not require that a structure be molded from one piece of material (which applicant seems to be inferring and which seems to be shown in the drawings). Hence, the prior art clearly shows the

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housing being an integral part (meaning used: "formed as a unit with another part"). If applicant believes that the novelty of applicant's invention lies in the fact that the entire structure is molded from one material, then applicant should explicitly claim the molded structure. While one looks to the specification to further elucidate the invention as claimed, the structures from the drawings are not read into the claims.

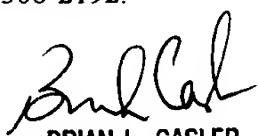
*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine Serke whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine Serke ⑨,  
June 27, 2003

  
BRIAN L. CASLER  
SUPERVISORY PATENT EXAMINER  
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